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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,767	11/16/2000	Dennis L. Bidney	35718/201902	5068

29122 7590 01/15/2003

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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/714,767	BIDNEY ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 25-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,7,8</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The rejection of Claims 2 and 4 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments to the claims.

The rejection of Claims 2-4 under 35 U.S.C. 102(b), is withdrawn in view of Applicant's amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 2-4 remain rejected and newly added claims 25-26 and 37-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/2002. Applicants arguments filed October 23, 2002 have been considered but are not deemed persuasive.

Applicant asserts that an improper standard has been applied because every species encompassed by the claimed invention need not be disclosed in the specification to satisfy the written description requirement and that 80% sequence identity is a very predictable structure (response page 11) when correlated with function i.e. a LOX like activity (response page 12). Applicant further asserts that sequences that hybridize to SEQ ID NO: 3 or that have 50 contiguous nucleotides to SEQ ID NO: 3 and that also have LOX like activity are therefore in

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possession of the necessary common attributes that would allow a person of ordinary skill to envision the invention (response page 13).

Recitation of 80% sequence identity, or hybridization to SEQ ID NO: 3 under low stringency conditions, or possession of 50 contiguous nucleotides of SEQ ID NO: 3, does not meet the written description requirement. Description of what a sequence does rather than its composition is not a description of the sequence. Applicant has not described structural elements that are common among and unique to the claimed genus of nucleic acid molecules, nor has Applicant described a representative number of nucleic acid molecules of the claimed genus. Applicant's description of the single nucleic acid molecule of SEQ ID NO: 3 does not provide adequate written description for the claimed invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/2002 as applied to Claims 2-4 and 7. Applicants arguments filed October 23, 2002 have been considered but are not deemed persuasive.

Applicant argues that a declaration was filed 7/23/02 stating that the cDNA was deposited with ATCC. (response, page 14). However, the attorney of record over his or her signature, must also state that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, in order to satisfy the deposit requirements. See 37 CFR 1.808.

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Claims 2-4 remain rejected and newly added claims 25-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to the sunflower nucleic acid molecule of SEQ ID NO: 3, a DNA construct comprising said nucleic acid molecule operable linked to a promoter and a transformed host cell comprising said DNA construct. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/2002. Applicants arguments filed October 23, 2002 have been considered but are not deemed persuasive.

Applicant asserts that the apparent suggestion that working examples are required to enable the instant invention is improper (response page 15) and that the specification provides sufficient guidance to enable the genus of sequences encompassed by the claims by means of functional variance to specific structural parameters i.e. 80% sequence identity, hybridization to SEQ ID NO: 3, and possession of at least 50 contiguous nucleotide sequences of SEQ ID NO: 3 and comprising LOX like activity (response page 16). Applicants further assert that the amount of experimentation required to enable the invention is not excessive and can be achieved in a two step procedure encompassing generating a nucleotide sequence that has 80% sequence identity to SEQ ID NO: 3; or isolating a sequence that hybridizes to SEQ ID NO: 3 under low stringency conditions of unspecified length of time for hybridization and wash; or generating a nucleotide sequence that has at least 50 contiguous nucleotides in common with SEQ ID NO: 3 and testing for LOX like activity (response page 17). Applicant does not provide adequate guidance for making any functional variants to specific structural parameters; i.e. 80% sequence identity to

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SEQ ID NO: 3, hybridization under low stringency and wash conditions of unspecified length of time, and possesses at least 50 contiguous nucleotide sequences of SEQ ID NO: 3.

Applicants asserts (response page 17) that the Broun *et al.* reference teaches away from making substitutions that conserve function of the LOX polypeptide because it teaches substitutions that are not conservative and that the location of the substituted residues is strictly conserved among oleate desaturases. However, this teaching of Broun only highlights the enablement rejection, namely that Applicant has not taught those residues that should be avoided when making changes conservative or otherwise. Since Applicant has not taught which sequences of SEQ ID NO: 3 when changed would conserve LOX activity, Applicant has not taught vectors and cells comprising said sequences.

Applicant asserts that a variety of eukaryotic expression systems comprising insect, yeast, animal, or plant cells can be used to express the nucleotide sequence of interest. Applicant asserts that the introduction of nucleic acids into said cells is routine in the art (response page 18). Applicant has not demonstrated any expression of SEQ ID NO: 3 in any cell type other than the endogenous expression in plants. The use of animal and insect cell expression systems would be problematic because of codon biases inherent in these expression systems. Further, Applicant provides no guidance for the selection of an animal cell type that would best express the nucleic acid of the invention. Moreover, Applicant claims integration of the DNA of the invention into the genome of a cell, whereas the specification recites ligation of the DNA of the invention into an autonomous replicating expression vector.

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Claims 37-41, newly added, are rejected under 35 U.S.C. 102(b) as being anticipated by Rance *et al.* (PNAS, USA Vol. 95 pp. 6554-6559, May 1998). This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/2002. Applicants arguments filed October 23, 2002 have been considered but are not deemed persuasive.

The hybridization conditions recited by Applicant allow for hybridization of a broad range of nucleotide sequences. Further, the high stringency wash does not specify any length of time such that a brief wash would not remove away sequences that were bound non-specifically or have only a low sequence identity to SEQ ID NO: 3.

Rance teaches a LOX gene, a promoter, and a transformed host cell (page 6555 column 2, lines 51-67).

Thus, the reference discloses the all the limitations of the instant claims 37-41.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Tiffiany Tabb, whose telephone number is (703) 605-1238.

Russell Kallis Ph.D.
January 6, 2003



AMY J. NELSON, PH.D.
SUPERVISORY PATENT EXAMINER
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